

Attorney Docket No.: 330310.00101
Customer No. 27160

U.S. Patent Application No.
10/669,441

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re Application of:

Leland SHAPIRO

Application No.: 10/669,441

Filed: September 25, 2003

For: INHIBITORS OF SERINE PROTEASE
ACTIVITY, METHODS AND
COMPOSITIONS FOR TREATMENT
OF NITRIC OXIDE INDUCED
CLINICAL CONDITIONS

Group Art Unit: 1614

Examiner: Not Yet Assigned

Confirmation No.: 4274

Atty. Dkt. No.: 330310.00101

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

February 8, 2005

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

In compliance with the duty of disclosure under 37 C.F.R. §1.56 and in accordance with the practice under 37 C.F.R. §§1.97 and 1.98, the Examiner's attention is directed to the documents listed on the enclosed Forms PTO/SB/08A and PTO/SB/08B. Please note that these documents were all considered in related application 09/518,097, filed March 3, 2000; now U.S. Patent No. 6,489,308, issued December 3, 2002. For the convenience of the Examiner a partial copy of the above patent with the listed references is enclosed. The citation numbers have been marked on the patent for ease of comparison.

FORMAL MATTERS

In accordance with 37 C.F.R. § 1.97(b)(3), since a first Official Action on the merits of the subject application has not yet been issued, neither a certificate, petition nor payment of a fee is believed to be required for this Information Disclosure Statement. However, the Commissioner is hereby

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U.S. Patent Application No.
10/669,441

authorized to charge any fee which may be required in connection with this paper to Deposit Account No.
50-1710.

CONCLUSION

It is respectfully requested that the above information be considered by the Examiner and that a copy of the enclosed Forms PTO/SB/08A and PTO/SB/08B be returned indicating that such information has been considered.

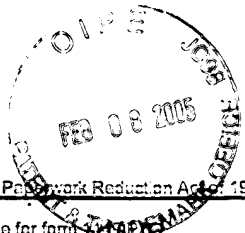
Applicant's undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3500. All correspondence should continue to be directed to our address given below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Serge Sira", written over a horizontal line.

Serge Sira, PH.D.
Attorney for Applicant
Registration No. 39,445

Patent Administrator
KATTEN MUCHIN ZAVIS ROSENMAN
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Chicago, Illinois 60661-3963
(202) 625-3500



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Sheet 1 of 17

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	1	US- 4,021,472 A	05/1977	Fujii et al.	
	2	US- 4,051,842 A	10/1977	Hazel et al.	
	3	US- 4,140,122 A	02/1979	Kuhl et al.	
	4	US- 4,224,342 A	09/1980	Fujii et al.	
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	6	US- 4,310,533 A	01/1982	Uegai et al.	
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	11	US- 4,711,848 A	12/1987	Insley et al.	
	12	US- 4,713,224 A	12/1987	Tamhankar et al.	
	13	US- 4,732,973 A	03/1988	Barr et al.	
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	15	US- 4,788,603 A	11/1988	Fujimura et al.	
	16	US- 4,829,052 A	05/1989	Glover et al.	
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	18	US- 4,843,094 A	06/1989	Imaki et al.	
	19	US- 4,889,723 A	12/1989	Kim et al.	

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		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	20	WO 94/07525	04/1994			
	21	WO 95/28422	10/1995			
	22	WO 95/34538	12/1995			
	23	WO 96/12021	04/1996			
	24	WO 96/14067	05/1996			
	25	WO 97/03679	02/1997			

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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	26	US- 4,931,279 A	06/1990	Bawa et al.	
	27	US- 4,963,654 A	10/1990	Katunuma	
	28	US- 5,004,612 A	04/1991	Kim et al.	
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	45	WO 97/09346	03/1997			
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	47	WO 97/10222	03/1997			
	48	WO 97/10231	03/1997			
	49	WO 97/21690	06/1997			
	50	WO 97/24339	07/1997			

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	51	US- 5,486,470 A	01/1996	Darke et al.	
	52	US- 5,489,593 A	02/1996	Palmer et al.	
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	70	WO 97/31937	09/1997			
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	73	WO 97/45402	12/1997			
	74	WO 97/48706	12/1997			
	75	WO 97/49679	12/1997			

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	76	US- 5,663,416 A	09/1997	Kirschenheuter et al	
	77	US- 5,665,589 A	09/1997	Harris et al.	
	78	US- 5,700,779 A	12/1997	Goodfellow et al.	
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	80	US- 5,712,117 A	01/1998	Sprecher	
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	95	WO 98/06417	02/1998			
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	98	WO 98/21186	05/1998			
	99	WO 98/22098	05/1998			
	100	WO 98/22619	05/1998			

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	101	US- 5,861,380 A	01/1999	Gyorkos et al.	
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	112	WO 98/23565	06/1998			
	113	WO 98/24806	06/1998			
	114	WO 98/46597	10/1998			
	115	WO 98/49190	11/1998			
	116	WO 98/50342	11/1998			
	117	WO 98/50420	11/1998			

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Sheet	6	of	17
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	118	WO 98/56821	12/1998			
	119	WO 97/41231	08/1999			
	120	WO 99/43308	09/1999			
	121	WO 00/52034	09/2000			

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				Application Number	10/669,441
				Filing Date	September 25, 2003
				First Named Inventor	Leland SHAPIRO
				Art Unit	1614
				Examiner Name	Not Yet Assigned
Sheet	7	of	17	Attorney Docket Number	330310.00101

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	122	Aoki H, Akaike T, Abe K, Kuroda M, Arai S, Okamura R, Negi A, Maeda H. Antiviral effect of oryzacystatin, a proteinase inhibitor in rice, against herpes simplex virus type I in vitro and in vivo. Antimicrob Agents Chemother Apr. 1995; 39(4):846-9.	
	123	Auerswald et al., "Recombinant leech-derived trypsin inhibitor: construction, production, protein chemical characterization and inhibition of HIV-1 replication", Biol Chem Hoppe Seyler, 375(10):695-703 (1994).	
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	149	Schwartz, et al., "Antiviral activity of the proteasome on incoming human immunodeficiency virus type I", J Virol, 72(5):3845-50 (1998).	
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	151	Szeghy G, Kenyeres B. On the therapy of herpes simplex keratitis with heparin and trypsin. [Article in German] Klin Monatsbl Augenheilkd 1968; 153(6):827-30.	

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	152	Cilberto et al., 1985, Cell, 41:531-540.	
	153	Dery O. and Bunnett, N.W. Biochem Soc Trans 1999, 27, 246-254.	
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	162	Nathan, C. in FASEB J. 1992, 6, 3501.	
	163	Rehman, A. et al. in Br J Pharmacol, 1997, 122, 1702.	
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	172	Schini et al. in Circ Res 1994, 74, 24.	
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Substitute for form 1449 PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/669,441
				Filing Date	September 25, 2003
				First Named Inventor	Leland SHAPIRO
				Art Unit	1614
				Examiner Name	Not Yet Assigned
Sheet	15	of	17	Attorney Docket Number	330310.00101

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	202	Premack, B.A. et al., "Chemokine Receptors: Gateways to Inflammation and Infection", 1996, Nature Medicine 2:1174-1178.	
	203	Zhirnov O.P. et al., "Antiviral activity of proteinase inhibitors in cultured cells infected with alpha-viruses", Mol Gen Mikrobiol Virusol, 1985, (12):30-6.	
	204	Chesnokova N.B. et al., "Antiproteases in herpetic keratitis", Metab Pediatr Syst Ophthalmol, 1986;9(1):593-6.	
	205	Adelman S.F. et al., "Protease inhibitors suppress fibrinolytic activity of herpesvirus-transformed cells", J Gen Virol, 1982, 60(Pt 1):15-24.	
	206	Chesnokova N.B. et al., "Main proteolytic inhibitors in ocular herpes", Vopr Med Khim, 1981, 27(5):663-5.	
	207	Sharpstone D. et al., "Faecal alpha 1 antitrypsin as a marker of gastrointestinal disease in HIV antibody positive individuals", Gut, 1996, 38(2):206-10.	
	208	Patel et al., "The Role of Protease Drug During Apoptosis", 1996, FASEB J, 10(5):587-597.	
	209	Estaquier J., "Fas-mediated apoptosis of CD4+ and CD8+ T cells from human immunodeficiency virus-infected persons: differential in vitro preventive effect of cytokines and protease antagonists", 1996, Blood, 15;87(12):4959-66.	
	210	Shimizu, T. et al., "DNA Fragmentation induced by Protease Activation in P53-null Human Leukemia HL60 Cells Undergoing Apoptosis Following Treatment with the Topoisomerase I Inhibitor Camptothecin: Cell-Free System Studies", 1996, Exp Cell Res, 1:226(2):292-301.	
	211	Glynn et al., "Apoptosis induced by HIV Infection in H9 T Cells is Blocked by ICE-Family Protease Inhibition but not by a FAS(CD95) Antagonist", 1996, J. Immunol, 1; 157(7):2754-2758.	

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				Application Number	10/669,441
				Filing Date	September 25, 2003
				First Named Inventor	Leland SHAPIRO
				Art Unit	1614
				Examiner Name	Not Yet Assigned
Sheet	16	of	17	Attorney Docket Number	330310.00101

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	212	Ooka, T., et al., "Protective effects of human urinary trypsin inhibitor against trypsin-induced relaxation in rat aorta", Crit care Med, 1996, 24(11): 1903-1907.	
	213	Novradovsky, A., et al., "Endothelial Nitric Oxide Synthase as a Potential Susceptibility Gene in the Pathogenesis of Emphysema in alpha1-Antitrypsin Deficiency", 1999, Am J Respir Cell Mol Biol, 1:20(3):441-447.	
	214	Cordiali Fei et al., "Behavior of several 'progression markers' during the HIV-Ab seroconversion period. Comparison with later stages", 1992, J Biol Regul Homeost Agents, 6(2):57-64.	
	215	Lima et al., "Mucosal injury and disruption of intestinal barrier function in HIV-infected individuals with and without diarrhea and cryptosporidiosis in northeast Brazil", 1997, Am J Gastroenterol, 92(10):1861-6.	
	216	Banfi et al., "Tumor-associated trypsin inhibitor in induced and acquired immunodeficiency. Studies on transplanted and HIV-infected patients", 1991, Scand J Clin Lab Invest 51, Suppl, 207:55-8.	
	217	Deam et al., "Alpha 1-antitrypsin phenotypes in homosexual men", 1989, Pathology, 21(2):91-2.	
	218	Pezzilli et al., "Serum pancreatic enzymes in HIV-seropositive patients", Dig Dis Sci, 1992, 37(2):286-8.	
	219	Tang et al., "Inactivation of HIV-1 by trypsin and its use in demonstrating specific virus infection of cells", 1991, J Virol Methods, 33(1-2):39-46.	
	220	Glozman, "Immunologic functions of enzyme therapy of patients with orchiepidymitis", 1990, Antibiot. Khimioter, 35(7):50-52.	
	221	Franzusoff, et al., "Biochemical and genetic definition of the cellular protease required for HIV-1 gp160 processing", 1995, J Biol Chem, 270(7):3154-9.	

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Complete if Known

Application Number	10/669,441
Filing Date	September 25, 2003
First Named Inventor	Leland SHAPIRO
Art Unit	1614
Examiner Name	Not Yet Assigned
Attorney Docket Number	330310.00101

Sheet	17	of	17
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	222	Gu et al., "Furin is important but not essential for the proteolytic maturation of gp160 of HIV-1", FEBS Lett. 1995, 365(1):95-7.	
	223	Bukrinskaia A.G., "Suppression of rotavirus SA-11 reproduction by protease inhibitors in cell culture", Vopr Virusol, 1987, 32(1):71-4.	

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